REMARKS

At the time the current Official Action was mailed, claims 1-24 were pending. The Examiner rejected claims 1-24. By the present response, Applicants have added claim 25, which contains no new material. Reconsideration of the application in view of the remarks set forth below is respectfully requested.

Information Disclosure Statement

In the Office Action dated July 19, 2005, the Examiner stated the following:

> The listing of references in the specification is not a proper disclosure statement. 37 C.F.R. § 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the Examiner on form PTO-892, they have not been considered.
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> In particular, US Patent No. 4,714,341; 5,482,036; 4,911,167; and 5,64505 [sic] are listed in the specification and not the IDS.

Office Action, p. 2.

Applicants presently submit an IDS listing, among other references, U.S. Patent Nos. 4,714,341; 5,482,036; 4,911,167; and 5,645,059 pursuant to 37 C.F.R. § 1.98(b) and MPEP § 609.04(a).

Rejection Under 35 U.S.C. § 101

In the Office Action, the Examiner rejected claims 1-13 under 35 U.S.C. § 101 as "not supported by either a specific and substantial asserted utility or a well established utility." Office

Action, page 2. Specifically, with regard to independent claim 1, the Examiner stated the following:

> Claim 1 specifies a method to measure a physiological parameter. However, Claim 1 does not result in a physical transformation nor does it appear to provide a useful, concrete and tangible result. Specifically, it does not appear to produce a tangible result because merely measuring a physiological parameter is nothing more than a computation within a processor. It fails to use or make available for use the result of the determination to enable its functionality and usefulness to be realized. Additionally, the asserted practical application in the specification of the method to measure a physiological parameter is for displaying the result to the user. The practical application is not explicitly recited in the claims nor does it flow inherently therefrom. Therefore, Claim 1 appears non-statutory.
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> Claims 2-13 further limit Claim 1 but also do not specifically or inherently produce tangible results from the method steps.
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> Office Action, pages 2-3.

Legal Precedent

According to the Supreme Court, Congress intended statutory subject matter to "include anything under the sun that is made by man." *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09; 206 U.S.P.Q. 193, 197 (1980). Indeed, exclusions of statutory subject matter are limited to laws of nature, natural phenomena and abstract ideas. *See Diamond v. Diehr*, 450 U.S. 175, 185; 209 U.S.P.Q. 1, 7 (1981). Other than these specific exceptions, therefore, nearly anything man made is statutorily patentable subject matter under 35 U.S.C. §101.

In determining when process or method claims include statutory subject matter, the Supreme Court in *Diehr* stated that "[t]ransformation and reduction of an article 'to a different

state or thing' is the clue to the patentability of a process claim that does not include particular machines." *See id.* 450 U.S. at 183-185, 209 U.S.P.Q. at 6. In addition to the Supreme Court's transformation and reduction test, the Federal Circuit has developed a second test which may also be used to determine if a claim recites statutory subject matter, namely does the claim produce a "useful, concrete, and tangible result." *In re Alappat*, 31 U.S.P.Q.2d 1545, 1557 (Fed. Cir. 1994) (*en banc*). The Federal Circuit further elaborated on this second test by holding that one must look to "the essential characteristics of the subject matter, in particular, its practical utility." *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 U.S.P.Q.2d 1596, 1602 (Fed. Cir. 1998).

However, explaining this "useful, concrete, and tangible" test, the Federal Circuit has stated "the dispositive inquiry is whether the claim *as a whole* is directed to statutory subject matter." *In re Alappat*, 31 U.S.P.Q.2d at 1557. Indeed, there has been no requirement from Congress, the Supreme Court, or the Federal Circuit mandating that a *specific final result* be shown for a claim to qualify under 35 U.S.C. 101. *See id.* Rather, the Federal Circuit has specifically stated "the *Alappat* inquiry simply requires an examination of the contested claims to see if the claimed subject matter *as a whole* is a disembodied mathematical concept representing nothing more than a 'law of nature' or an 'abstract idea,' or if the mathematical concept has been reduced to *some practical application rendering it 'useful'*." *AT&T Corp. v. Excel Communications, Inc.*, 50 U.S.P.Q.2d 1447, 1451 (Fed. Cir. 1999) (Emphasis added). Therefore, if a claim meets either the transformation and reduction test put forth by the Supreme Court, or if

the claim, read as a whole and in light of the specification, produces any useful, concrete, and tangible result, the claim meets the statutory requirements of 35 U.S.C. 101. *See id.*

Applicants respectfully assert that the independent claim 1, taken as a whole, recites statutory subject matter under 35 U.S.C. §101 because it produces a useful, concrete, and tangible result. The technique described in the present Application relates to removing motion artifacts from plethysmographic signals to enable more accurate determination of oxygen saturation. *See* Specification, p. 1, ll. 5-8. The technique takes advantage of the finding that a water absorbance signal, taken at a wavelength in the near infra-red (NIR) spectrum, is more sensitive to motion artifacts than to arterial pulsations. *See id.* at p. 7, ll. 6-9. A plethysmograph collected at this wavelength may be combined with plethysmographs collected at wavelengths associated with the absorbance signals of hemoglobin to create plethysmographs with lower noise. *See id.* at p. 7, ll. 22-24. The noise corrected plethysmographs may then be used in standard pulse oximetry algorithms to calculate physiologically important parameters, such as pulse rate or oxygen saturation. *See id.* at p. 1, ll. 1-20.

Accordingly, independent claim 1 recites, *inter alia*, "obtaining a first signal . . . at a first wavelength . . . , wherein at said first wavelength water is a dominant absorber . . . ; obtaining a second signal . . . at a second wavelength . . . , wherein at said second wavelength hemoglobin is a dominant absorber . . . ; combining said first signal and said second signal *to generate a combined signal comprising a plethysmograph* . . . having a signal portion corresponding with motion related events that is smaller than that present in . . . said second signal." (Emphasis

added). Applicants assert that the plethysmograph generated by combining the signals via the method recited in claim 1 is a useful, concrete, and tangible result. Indeed, the generated plethysmograph has many practical utilities and is not merely a concept. For example, the noise corrected plethysmograph may be used for the determination of pulse rate as recited in claim 11, or used in the determination of oxygen saturation, as recited in claim 13. Accordingly, Applicants respectfully request withdrawal of the rejection of independent claim 1, as well as all claims dependent thereon, under 35 U.S.C. §101.

Rejections Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1-4, 8-16, and 20-24 under 35 U.S.C. § 102(b) as being unpatentable over Diab et al. (U.S. Patent No. 6,501,945 B2)("Diab"). In rejecting these claims, the Examiner stated:

> Claims 1-4, 8-16, and 20-24 rejected under 35 U.S.C. 102(b) as being anticipated by Diab et al. (US Patent 6,501,975 B2). Diab et al. discloses the same invention including a method and apparatus for measuring a physiological parameter. Diab et al. discloses a pulse oximeter comprising two light emitting diodes that emit light in the red and infrared wavelengths (column 27, lines 5-1 1), a photodetector (column 27, line 8), and a microprocessor (column 28, line 22). Diab et al. teaches that the two detected signals include a desired portion and an undesired portion (column 10, lines 3-9) caused by motion (column 10, line 13). Diab et al. further teaches that the microprocessor combines the two light signals (column 10, lines 14-17).
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> Office Action, pages 2-3.

The Examiner also rejected claims 1-6, 8, 11-18, and 21-24 as being unpatentable over Pologe (U.S. Patent No. 5,297,548)(" Pologe"). In rejecting these claims, the Examiner stated:

> Pologe discloses the same invention including a method and apparatus for non-invasive photoplethysmographic measurement of blood analytes. Pologe discloses a pulse oximeter system (column 1, line 26) comprising a plurality of

> light emitting devices (column 4, lines 5-6), at least one corresponding light detector (column 4, lines 6-7), and a data processing circuit (column 6, line 19). Pologe teaches that the data received by the probe can include a noise component caused by motion (column 5, lines 29-32). Pologe further teaches that the data processing circuit computes a ratio of two light signals (column 6, lines 54-59 and figure 4, reference 404).
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> Office Action, pages 4-5.

Applicants respectfully traverse these rejections. Anticipation under 35 U.S.C. 102 can be found only if a single reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 U.S.P.Q. 773 (Fed. Cir. 1985). For a prior art reference to anticipate under 35 U.S.C. 102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). To maintain a proper rejection under 35 U.S.C. 102, a single reference must teach each and every element or step of the rejected claim. *Atlas Powder v. E.I. du Pont*, 750 F.2d 1569 (Fed. Cir. 1984). Thus, if the claims recite even one element not found in the cited reference, the reference does not anticipate the claimed invention.

Diab does not teach obtaining a water absorbance signal for measuring motion artifacts.

Applicants respectfully assert that Diab fails to anticipate independent claims 1 and 14. As discussed above, the present Application relates generally to using a plethysmograph of a water absorbance signal to correct plethysmographs of hemoglobin absorbance signals for noise artifacts. The water absorbance signal is highly dependent on motion noise, and it gives a good reference signal for removing this noise. As stated in the application, "where water is the predominant absorber, the arterial pulsations diminish and the measured signal becomes largely

due to motion related events." *See* Specification, p. 7, ll. 20-21. Accordingly, independent claims 1 and 14 both recite, "obtaining a first signal . . . at a first wavelength . . . , wherein at said first wavelength *water* is a dominant absorber of electromagnetic energy in the tissue." (Emphasis added).

In contrast to measuring a noise signal based on a water absorbance, as in the technique discussed above, Diab calculates an artficial noise signal from signals measured at two wavelengths associated with the absorbance spectrum of *hemoglobin*, not water. *See* Diab, col. 3, ll. 39-42, and col. 9, l. 62 – col. 10, l.11. This artificial noise signal is then used to correct the signals of interest by an adaptive noise cancellation algorithm. *See* Diab, col. 3, ll. 46-58, and Fig. 4. In fact, Diab admits that "if the actual undesired signal portion . . . were *a priori* available, techniques such as adaptive noise canceling would not be necessary." *See* Diab, col. 11, ll. 28-31. Thus, Diab does not disclose obtaining or using a water absorbance signal, as recited in claims 1 and 14 of the present application.

While Diab does disclose that a third wavelength may be collected to enable a ratiometric determination of oxygen saturation, Diab notes that this signal is processed in an identical fashion to the other two signals. *See* Diab, col. 28, l. 66 – col. 29, l. 13. Accordingly, this third wavelength does not correspond to a water absorbance. Indeed, Diab notes that "typical wavelength values chosen are λa = 650 nm, λb = 685 nm, and λc = 940 nm." *See* Diab, col. 29, l. 66 – col. 30, l. 1. In contrast, as set forth in the present Application, wavelengths in the range of

1100 to 1400 nm and from 1500 – 1850 nm are utilized for the collection of a water absorbance signals related to motion artifacts. *See* Application, p. 12, ll. 5-8.

As discussed above, Diab does not disclose the collection of a signal corresponding to a water absorbance as in independent claims 1 and 14 of the current application. Therefore, Applicants respectfully assert that Diab fails to anticipate independent claims 1 and 14, or their dependent claims 2-4, 8-13, 15, 16, and 20-24.

Pologe does not teach combining the signals to generate a plethysmograph with lower noise.

As discussed above, the present Application discloses combining a water absorbance signal with a hemoglobin absorbance signal to create a plethysmograph with lower noise. Accordingly, independent claims 1 and 14 both recite "combining said first signal and said second signal to generate a *combined signal comprising a plethysmograph* having a signal portion corresponding with motion related events that is smaller than that present in said first signal or said second signal." (Emphasis added).

Applicants respectfully assert that Pologe fails to anticipate independent claims 1 and 14. Indeed, Applicants assert that Pologe merely uses the water signal as the second wavelength to directly calculate the concentration of hemoglobin (tHb) using a two equation system. *See* Pologe, col. 7, ll. 34-44, and col. 8, ll. 6-14. Pologe does not teach "combining said first signal and said second signal to generate a *combined signal comprising a plethysmograph*," as recited in claims 1 and 14. Indeed, according to Pologe, no combined plethysmographic signal having a

reduced noise component is ever generated. In fact, the only reference to noise reduction in Pologe is believed to be the statement that "existing pulse oximeter circuits make use of various filtering techniques to minimize the impact of noise . . . analogous to that used in the arterial blood monitoring system 100 and are therefore not described in detail herein." *See id.*, col. 5, ll. 36-43. While Pologe does discuss the collection of a signal at a third wavelength, it is only for use in a three equation system to solve for both tHb and SaO_2 in order to determine oxygen saturation. *See* Pologe, col. 9, l. 55-col. 10, l. 1, and eqns. 10 and 11.

As discussed above, Pologe does not disclose the generation of a combined signal having lower motion related noise as recited in independent claims 1 and 14 of the current application. Therefore, Applicants respectfully assert that Pologe fails to anticipate independent claims 1 and 14, or their dependent claims 2-6, 8, 11-13, 15-18, and 21-24.

In view of the arguments set forth above, Applicants assert that independent claims 1 and 14 are allowable over either Diab or Pologe. Accordingly, Applicants request that the Examiner withdraw the rejections of claims 1 and 14, and the claims depending therefrom under 35 U.S.C. § 102. Further, Applicants request that the Examiner provide an indication of allowance for claims 1 and 14 and the claims depending therefrom.

Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected dependent claims 7 and 19 under 35 U.S.C. § 103(a) as being obvious over Pologe in view of Jöbsis (U.S. Patent No. 4,805,623) ("Jöbsis"). In rejecting these claims, the Examiner stated:

> Pologe discloses the invention substantially as claimed with the exception of using a wavelength of approximately 1185 nm. However, Pologe teaches any three wavelengths may be used (column 9, lines 29-3 1) if they meet the criteria where water is transparent at one wavelength (such as 810 nm) and detected at the other wavelength (such as 1270 nm) (column 4, lines 3 0-32). Jöbsis discloses the absorbance curve for water where water experiences three peak absorbance at 980 nm-n, 1200 nm, and 1400 nm (figure 6). The absorbance at 1200 nm meets the criteria as specified by Pologe and is viewed as approximately 1185 nm.
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> Office Action, pages 5-6

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. To establish a *prima facie* case, among other requirements, the Examiner must show that the combination includes *all* of the claimed elements. *Ex parte Clapp*, 227 U.S.P.Q. 972 (Bd. Pat. App. & Inter. 1985). As discussed above, Pologe does not teach combining a water absorbance signal with a hemoglobin absorbance signal to create a noise corrected plethysmograph, as recited in independent claims 1 and 14 of the current application. Jöbsis whether considered alone, or in a theoretical combination with Pologe, does not obviate this deficiency. Thus, the Examiner's rejection of claims 7 and 19, which respectively depend from claims 1 and 14 is improper. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection and provide an indication of allowance for claims 7 and 19.

New Claim

As set forth above, the Applicants added new claim 25. For the reasons discussed in detail above and other claim features, the Applicants believe this claim is patentable over the cited references and in condition for allowance. Therefore, the Applicants request that the Examiner allow the newly added claim 25.

Conclusion

In view of the remarks set forth above, Applicants respectfully request withdrawal of the Examiner's rejections and allowance of claims 1-25. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date: October 19, 2006

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